

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

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13 MAR 2004
NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

11.11.2004

Applicant's or agent's file reference
ES/13310.4

IMPORTANT NOTIFICATION

International application No.
PCT/CA 03/01429

International filing date (day/month/year)
19.09.2003

Priority date (day/month/year)
20.09.2002

Applicant
MEDINNOV, INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ES/13310.4	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/CA 03/01429	International filing date (day/month/year) 19.09.2003	Priority date (day/month/year) 20.09.2002
International Patent Classification (IPC) or both national classification and IPC C12Q1/00		
Applicant MEDINNOV, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 19.04.2004	Date of completion of this report 11.11.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Jenkins, G Telephone No. +31 70 340-2608 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01429**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-29 as originally filed

Claims, Numbers

1-45 received on 13.09.2004 with letter of 07.09.2004

Drawings, Sheets

1/21-21/21 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

~~4. The amendments have resulted in the cancellation of:~~

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01429**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4-8,11-26,30-34,37-45
	No: Claims	1-3,9,10,27-29,35,36
Inventive step (IS)	Yes: Claims	23-26
	No: Claims	1-22,27-45
Industrial applicability (IA)	Yes: Claims	1-45
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 The following documents (D1-D2) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: PLEGGE ET AL: 'Analysis of ternary mixtures with a single dynamic microbial sensor and chemometrics using a nonlinear multivariate calibration', ANAL CHEM, 01. June 2000, vol. 72, no. 13, pages 2937 to 2942,

D2: US 5312590 A 1994.05.17 998, vol. 17, no. 6-7, pages 1111 to 1128.

2 NOVELTY

- 2.1 The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claim 1-3,9,10,27-29,35,36 is not new in the sense of Article 33(2) PCT.

- 2.1.1 D2 discloses (the references in parentheses applying to this document): a device suitable for measuring the concentration of two related analytes that are substrates for a common enzyme comprising a support base (figure 3); a mixed electrode system comprising a platinum working electrode, a platinum auxiliary electrode, and a silver reference electrode (column 4, lines 22-25,64-69; claim 11); an enzymatic reaction means (glucose oxidase: column 7, lines 9-24); a detector (figure 9); a data processor capable of converting amplified signals into numerical data representing the concentration of two analytes; a layer of a TTF/Nafion on which glucose oxidase is bound (column 7, lines 9-24); a protective polycarbonate membranae (column 7, lines 9-24), and a reagent well (figure 3). Ferrocene mediators are also disclosed (column 2, lines 25-27). In accordance with the PCT Guidelines Section IV 5.23, 12.05, the intended use of the apparatus cannot be used here to establish novelty (i.e. placing the enzyme in contact with a liquid sample containing two related analytes), since the apparatus of D2 could also be contacted with two related analytes (e.g. glucose

and mannose) and its processor used to convert the electronic signals into the concentration of each analyte. The subject-matter of claims 1-3,9,10,27-29,35,36 is therefore not new (Article 33(2) PCT).

2.1.2 The subject-matter of method claims 4-8,11-26,30-34,37-45 is considered novel (Article 33(2) PCT).

3 INVENTIVE STEP

3.1 The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claims 4-8,11-22,30-34,37-45 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1.1 The subject-matter of claims 4-8,11-22 merely adds routine modification options to the subject-matter of claim 1 and is therefore obvious to a person skilled in the art. For this reason the subject-matter of claims 4-8,11-22 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1.2 The subject-matter of claims 30-34,37-45 merely adds routine modification options to the subject-matter of claim 27 and is therefore obvious to a person skilled in the art. For this reason the subject-matter of claims 30-34,37-45, does not involve an inventive step in the sense of Article 33(3) PCT.

3.2 The subject-matter of claims 23-26 is considered inventive under Article 33(3) PCT.

3.2.1 The subject-matter of claim 23 is considered inventive under Article 33(3) PCT. Here, D1 is considered the closest prior art. This document discloses (the references in parentheses applying to this document): a method for simultaneously measuring the concentration of acetate, L-lactate and succinate involving a) reacting a plurality of reference samples having known concentrations and proportions of said related analytes with microorganisms (p. 2939, column 1, paragraph 2), b) establishing a kinetic profile having at least two points for each of said plurality of reference samples (p. 2940), c) reacting a

test sample with microorganisms and determining concentrations of related components (table 2).

- 3.2.1.1 The additional technical feature of claim 23 over D1 is that the simultaneous multi-species analyte determination is achieved using a single enzyme, rather than a mixture of enzymes (e.g. microorganism cells).
- 3.2.1.2 The technical effect associated with this modification is a simpler assay.
- 3.2.1.3 The problem to be solved by the present invention may therefore be regarded as the provision of a simpler assay for simultaneously measuring the concentration of two related analytes.
- 3.2.1.4 The solution to this problem is to use a single enzyme, rather than a mixture of enzymes.
- 3.2.1.5 The solution to the problem is not suggested or derivable in an obvious way from the prior art. Therefore, the subject-matter of claim 23 is inventive in the sense of Article 33(3) PCT. Claims 24-26 are dependent on claim 23, and their subject-matter is therefore also inventive (Article 33(3) PCT),

4 INDUSTRIAL APPLICABILITY

- 4.1 The subject-matter of claims 1-45 is industrially applicable in the field enzyme electrodes (Article 33(4) PCT).